

# Interview: Dharminder S. Chahal, CEO & Leonard Kruimer, CFO, SkylineDx, The Netherlands

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*The CEO and CFO of SkylineDx talk about the company's latest product, the MMprofiler, a prognostic test to determine the level of risk of a multiple myeloma. Also discussed are SkylineDx's future plans and how private funding capital is fostering a renaissance of the Dutch biotech sector. Personalized medicine will improve the survival and quality of life of patients, and diagnostic tests help physicians tailor the treatment to the specific needs of each individual.*

**SkylineDx is focused on the development and commercialization of innovative gene signature-based diagnostic tests. What makes the company so attractive in the Netherlands as well as internationally?**

**DC:** Our lead product, the MMprofiler, is a prognostic test to determine the level of risk of a multiple myeloma and really helps doctors and patients improve treatment. We also have ambitious growth plans: we are witnessing a big trend in using big data and bioinformatics and are one of the few companies developing high-value complex molecular diagnostics.

**LK:** We manage state-of-the-art bioinformatics and are able to develop disease-specific tests, which can help physicians personalize a treatment plan for patients to make it more effective. This is key given the current trend towards increasingly personalized healthcare and use of genomic data. What is attractive is that we were able to develop a test that is very effective. The challenge is to identify in

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what other areas we can develop tests, as it has tremendous potential to personalize medicine.

### **Why is the MMprofiler a game-changer in the industry?**

**DC:** Today complex molecular diagnostics is only done in a few labs in the world; our business model brings this type of diagnostics to a regular lab through an IT infrastructure. This enables a hospital to carry out complex molecular diagnostics by themselves instead of sending the sample to a central lab.

### **You aim to make personalized medicines a reality, on a global scale. However, such technologies and treatments are notoriously expensive. How are you keeping down costs to make this dream an economically feasible reality?**

**LK:** The cost of treatment for a person with a specific disease is more than EUR 100,000 per year. Our test represents approximately 3 percent of that amount. If you can ensure upfront that the total cost of treatment can be minimized for the average patient population, it's a good cost-value relationship. Once the test is developed it's about increasing the volume, so the average cost per test will drop dramatically.

### **What are your marketing plans for the MMprofiler in the Netherlands as well as worldwide?**

**DC:** We launched the product in summer 2015 only in the Netherlands without a big commercial push, as we are interested in getting into the guidelines. Now we are working on receiving the CE mark, which we expect to get in November, so we'll be more broadly available. In the US, we'll seek FDA clearance, so we'll probably be available on the market mid-2016. We are also working on guideline inclusion and reimbursement for selected European countries and the US.

### **How far are the discussions for reimbursement in the Netherlands?**

**LK:** It is not reimbursed by the insurance companies yet. Our goal is to make the product available, so it can be used for research purposes by key opinion leaders and others who can start to work with it as well as help gain market acceptance.

### **Are there any other markets you are looking at?**

**DC:** We are looking at entering further markets through distributors. We are currently in talks with potential distributors in Latin America and Asia, but our main markets are North America and Europe.

### **Could you tell us a bit more about another of your products, the AMLProfiler?**

**DC:** The AMLprofiler is a diagnostic test that makes the distinction between the various genetic forms of acute myeloid leukemia (AML). It's a legacy product, which receives some demand from developing countries. We are involved in a big trial in Brazil but have not pushed it in Europe nor in the US yet, because we need to do a full premarket approval trial and there is no business case for that.

### **What about the APprofiler?**

**LK:** The plan is to first commercialize the MMProfiler in Europe and in the US. We are also expanding our multiple myeloma franchise by developing new tests and markers that can also be predictive, which means they can predict which drug class works better for a patient. The APprofiler is still in research phase: we are conducting a clinical trial ongoing until mid-2016,

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which will provide a lot of data to start research. We are also actively seeking new opportunities in other disease areas, so are scouting all over the world leading academic institutions to see if they have IP or data available on diagnostics disease areas.

**DC:** We have developed disease-specific software. The common thread is the bioinformatics knowledge, a working method and a profiling platform, which is the box in which you put the disease-specific software. Without changing the working method and protocols and with the specific equipment, a lab can insert the test, send it to us and we send back a report instantly.

### **Moving forward, what is your strategy for further developing your products?**

**DC:** We are increasingly looking at oncology and have a cardio-vascular research project. We are also currently sourcing new pipeline projects: we started four months ago with a project and hope to have new ones next year.

### **SkylineDX has a strong collaboration network with local universities, patient organizations and hospitals in the Americas and Africa. How do these partnerships strengthen the company?**

**DC:** We are a commercial company but with a solid scientific background. We believe the growth of our products comes from good science, so scientific collaborations are very important. The most important partner today is the Erasmus University of Rotterdam: clinicians help us better understand myeloma and how our product can help. This relationship is key for product development, adoption and get the experts together.

### **How do you assess the atmosphere in the Netherlands in translating fundamental research into products?**

**LK:** Over the past five years we have seen interesting success stories we had not seen before, and these cases set examples for others to follow. There has thus been a change in mindset also at academic centers that translational research is very important.

**DC:** Basic research done in the Netherlands is very high, but the gap to take a finding and make it a marketable product is huge. However, the mindset is changing. Universities are in need of additional funding, so they tend to become more commercial, and there is a pool of entrepreneurs, financial backers and international venture capital (VC) companies that are highly interested in the sector. It all needs to come together. It's still far from perfect, but it's better than it was in the past.

### **Government funding has been drying up in recent years. Do you see private and VC funding helping companies move forward in the Netherlands?**

**DC:** Currently because of the success stories we have witnessed there is lot of risk capital available in the Dutch market. We have very successful VCs, which are raising new funds. For the coming years, I see good appetite for risk capital: this will help fill the gap left by the government. What I personally like is that it's smarter capital.

**LK:** Indeed, massive government funding may not always be the answer. Germany is a good example: in the nineties Germany set up biotech centers in Berlin and Munich. They invested significantly with limited results. Lack of government funding should not be an excuse for not developing companies. There is a risk: when a sector gets too much hype, momentum investors without specific knowledge join in. Qualified biotech investors will understand the risk/reward tradeoff. It's with this type of investors that you should grow. Our largest investor is a family office, but with extensive experience in biotech and with a long-term vision. This provides us with an

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excellent opportunity to grow.

**You both come from strong financial backgrounds, how does this give you an edge in leading SkylineDx forward?**

**LK:** As long as you manage the business, you have to be humble and respect the scientists who make it happen. We both have significant knowledge in a number of industries, have made lots of mistakes and learned a lot in previous positions and have a big bag of experience which allows you to look at risks, evaluate them quickly and take action very quickly.

**DC:** I'm an investment manager and have seen many success stories. In my opinion, it starts with the team: we started being six and now are 25, and I recruited all of them looking for people who could work as a team. We have a very good management team but also collaborate within and across the divisions. Personalized healthcare is a growing market niche, and we have the perfect infrastructure and capabilities to grasp the market opportunity.

**What are you most proud of so far?**

**DC:** We have grown from six to 25 people. We started with a research idea in multiple myeloma and developed it into a product in less than 2.5 years. The most rewarding is that we developed a diagnostic test that is able to diagnose multiple myeloma patients more accurately. In this way a more personalized treatment plan for patients can be designed, providing them better quality of life.

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